UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,840	11/06/2000	John A. Drewe	1735.0410002/RWE/BEC	8076

7590 07/03/2003

Sterne Kessler Goldstein & Fox PLLC
Attorneys at Law
Suite 600
1100 New York Avenue N W
Washington, DC 20005-3934

EXAMINER
ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
1625	21

DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/705,840	Applicant(s) DREWE ET AL.	
	Examiner Binta M. Robinson	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *13 and 14* is/are withdrawn from consideration.

5)☒ Claim(s) *42,44,45,63-65,75,78,80,81,92 and 93* is/are allowed.

6)☒ Claim(s) *1,4-7,9,13,21,26-28,30,32,33,46, 47, 50,51,53,54,57,60,64,65,79 and 84-90* is/are rejected.

7)☒ Claim(s) *25,34-38,40,41,66-72,76,77,82,83 and 91* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *19* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continuation of Disposition of Claims: Claims pending in the application are 1,5-7,9,13,14,16,18,21,25-28,30,32-38,40-42,44-47,50,51,53,54,57,60,63-72 and 75-93...

Detailed Action

The Final Office Action at paper no. 21 is vacated because it was not responsive to the amendment filed 12/12/02. The following office action below responds to the amendment filed 12/12/02.

The examiner will rejoin claims 6, 7, 9, 13, 16, 18, 21, 25, 46, 50,51, 53, 54, 57, and 60 into group I for examination since they were improperly restricted out and do read on the elected subject matter. However, the restriction requirement of group I is revised below such that: only R2 and R3 on the phenyl moiety of the ring core of formula II in claim 6 and all other claim drawn to a compound of formula II, form a pyrrole ring. All other radicals other than X that can equal to or result in a moiety containing a heteroaryl or heterocyclic moiety are restricted out. Also, for claim 1 and all other claims drawn to compounds of formula I, the B ring is an indolo ring where the N of the indolo ring system is separated by 4 carbons in the ring system from the X moeity.

(new objections and rejections)

Applicant is advised that should claim 75 be found allowable, claim 92 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicant is advised that should claim 75 be found allowable, claim 93 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 27 is rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the method of treating all inflammation diseases or drug resistant cancers related to a disorder responsive to the induction of apoptosis in an animal suffering therefrom or all drug resistant cancers, all disorders responsived to the induction of apoptosis in a mammal suffering therefrom, wherein said disorder is cancer, or all of the heteraryl or optionally substituted heterocyclic groups in claim 46. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement.

The applicant is referred to ***In re Wands***, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in ***Ex parte*** foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1)the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of the first Wands factor of breadth, the treatment of all diseases responsive to the induction of apoptosis in an animal with a compound of formula I are being claimed. In terms of the nature of the invention which is the second Wands factor, these compounds are useful as activators of caspases and inducers of apoptosis. In terms of the sixth Wands factor, the amount of direction provided by the inventor is poor, because the applicant does not test compounds for their affects on the specific diseases claimed. In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into

consideration, it is not seen where the instant claim is enabled by the instant application.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 7, 9, 13, 21, 4, 50, 51 53, 54, 57, and 60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not provide enablement for R R10-R14 equal to all heteroarylalkyl, heteroarylalkenly, heterocyclic or heteroarylalkynyl or heterocycloalkyl groups in claim 53 and for R1-R4 equal to all heteroarylalkyl, heteroarylalkenly, heterocyclic, heteroarylalkynyl or heterocycloalkyl groups as claimed in claim 6, R10- R14 in claim 16 equal to all heteroarylalkyl, heteroarylalkenly, heterocyclic, heteroarylalkynyl or heterocycloalkyl groups or R10 and R11 or R11 and R12 coming together to from all heteroaryl or heteroyclic groups, wherein in claim 9 and 18 R can equal all heterocycloalkyl, heterocyclic or heteroaryl groups, or in claim 46, R1-R4 independently equal to all heteroarylalkyl, heteroarylalkenly, heterocyclic o r heteroarylalkynl or heterocycloalkyl groups, and in claim 54, R equal to all heteroarylalkyl, heteroarylalkenly, heterocyclic o r heteroarylalkynl or heterocycloalkyl groups. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as

recited are broader than the scope of enablement. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to ***In re Wands***, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in ***Ex parte*** Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1)the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of factor 3 and 5, the state of the art and the level of predictablitiy in the art cannot be predicted with any certainty beyond what specific test compounds /compositions and/or additional therapeutic agents should be used and are likely to provide productive results beyond those therapeutic compounds/compositions and/or additional therapeutic agents taught in the specification

In terms of factors 4 and 6, the inventor provides no guidance beyond the therapeutic compound/compositions and/or therapeutic agents as taught in the

specification as previously mentioned. As a result one of ordinary skill in the art could not predict what other types of therapeutic compounds/compositions and/or additional therapeutic agents, other than those taught in the specification; and with regards to the 7th and 8th wands factor, while the existence of working examples are limited to the aforementioned compounds/compositions as taught in the specification, an indeterminate quantity of experimentation would be necessary to determine all potential therapeutic compounds/compositions' effects on the diseases claimed .

In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim(s) 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 33, lines 7-8, page 2 of the amendment at paper 18/D, the terms "Herceptin ® ", and "Rituxan ®" are indefinite because they are trademarks.

(old rejections)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 28 is rejected under 35 U.S.C. 112, first paragraph, for reasons of record at paper no. 15 because the specification, does not reasonably provide enablement for the method of treating all of the various cancers. No drug can treat all of these cancers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement.

The applicant is referred to ***In re Wands***, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in ***Ex parte*** Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1)the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In

re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of the first Wands factor of breadth, the treatment of a wide range of cancers with a compound of claim 1 is being claimed. In terms of the nature of the invention which is the second Wands factor, these compounds are useful in the treatment of various cancers. .In terms of the fifth Wands factor, the capase potency ranges from 7 which is poor to 364 which are great. There are massive differences in caspase potency for small changes in structure. For example, compound 97 has a 3 bromo instead of a 2 bromo and a methyl on the 4H-indolo ring. However, the caspase potency compound 7 whereas it is 364 for compound 95. The level of predictability regarding caspase potency is low. In terms of the sixth Wands factor, the amount of direction provided by the inventor is poor, because the applicant does not test compounds for their affects on the specific diseases claimed. The applicant must show tests results for the cancers claimed involving specific cell lines. In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

Claim 41 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 66. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper

after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 66 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 67. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 67 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 66. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 68 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 69. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 69 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 68. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 70 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 69. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 71 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 41. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 72 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 41. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5, 26, and 79 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the method of

treating all inflammation diseases or drug resistant cancers related to a disorder responsive to the induction of apoptosis in an animal suffering therefrom or all drug resistant cancers, all disorders responsived to the induction of apoptosis in a mammal suffering therefrom, wherein said disorder is cancer, or all of the heteraryl or optionally substituted heterocyclic groups in claim 46. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement.

The applicant is referred to ***In re Wands***, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in ***Ex parte*** foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1)the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).
In terms of the first Wands factor of breadth, the treatment of all diseases responsive to the induction of apoptosis in an animal with a compound of formula I are being claimed.

In terms of the nature of the invention which is the second Wands factor, these compounds are useful as activators of caspases and inducers of apoptosis. In terms of the sixth Wands factor, the amount of direction provided by the inventor is poor, because the applicant does not test compounds for their affects on the specific diseases claimed. In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim(s) 1, 5, 26, 27, 30, 32, 64, 65, 79 84-90 in part are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claims 1, 5, 26, and 79 in part, at paper no. 13C, the phrase "inflammation" is indefinite. It is unclear as to which inflammation diseases the applicant is referring to.

B. In claim 27, line 2, page 5, of the amendment at paper no. 13C, and claim 90, the term "cancer" is indefinite. What cancer is the applicant claiming?

C. In claim 32, lines 2-3, page 115, and all other occurrences of this term in claims 33the phrase "cancer chemotherapeutic agent" and "pharmaceutically acceptable salt of

said agent" are indefinite. What cancer chemotherapeutic agents are the applicant claiming?

D. In claim 30, lines 1-2, page 115, the phrase "drug resistant cancer" is indefinite. What drug resistant cancers is the applicant claiming?

E. In claim 64, lines 2-3, page 131, the term " cancer chemotherapeutic agent, or a pharmaceutically acceptable salt of said agent" is indefinite. Which cancer chemotherapeutic agent or salt thereof is the applicant claiming?

F. In claim 65, lines 7-8, page 3 of the amendment at paper 18/D, the terms "Herceptin ® ", and "Rituxan ®" are indefinite because they are trademarks.

Response To Applicant's Remarks

112, first paragraph rejection of claim 28

The applicant's provision of articles in support of Applicant's postion that claim 28 is enabled does not overcome the enablement rejection. It is not established in the art for one drug to treat all of these cancers. As the examiner stated earlier in the action, claim 28 violates several Wands factors. The applicant has asserted that the examiner has not met her burden of establishing that the claimed invention is not enabled. However, the burden is on the applicant to enable the invention, and this burden clearly, has not been met. In terms of the fifth Wands factor, the capase potency ranges from 7 which is poor to 364 which are great. There are massive differences in caspase potency for small changes in structure. For example, compound 97 has a 3 bromo instead of a 2 bromo and a methyl on the 4H-indolo ring. However, the caspase potency compound 7 whereas it is 364 for compound 95. The level of predictability

regarding caspase potency is low. In terms of the sixth Wands factor, the amount of direction provided by the inventor is poor, because the applicant does not test compounds for their affects on the specific diseases claimed. The applicant must show tests results for the cancers claimed involving specific cell lines. In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

Duplicate claim objections

The applicant's traverse the duplicate claim objections of claims 41, 66, 67, 68, and 69 on the assertion that claims 66, 68, 71 and 72 substantially limit claim 41. However, this is not the case. Limitations regarding the excipient or carrier in a pharmaceutical composition do not substantially limit the claim, since such limitations add no patentable weight to the claim.

112, first paragrah rejection of claims 1, 5, 26, and 79

The applicant traverses this rejection asserting that there is a big distinction between "cancer" per se and drug resistant cancer that obviates the rejection. However, the applicant has not demonstrated in the specification that the claimed invention can treat all of the various drug resistant cancers with specific experimental data on the treatment of these various individual cancers. The applicant asserts that the examiner's arguments are rextremely general and misdirected and says, "for

example, the treatement of all diseases responsive to the induction of apoptosis in an animal with a compound of formula I" is not being claimed. However, clearly, the applicant is claiming the ability to be able to treat any disease responsive to the induction of apoptosis in an animal, and the applicant has not demonstrated in the specification, that the claimed invention can treat all of the diseases responsive to the induction of apoptosis in an animal with a compound of formula I. The applicant has not presented evidence of sound scientific reasos why one of ordinary skillin the art would believe that claim 30 is fully enabled. The burden is on the **applicant**, not the examiner, to enable his/her invention. There is no reason to believe that the applicant's invention, can treat the broad class of diseases responsive to the induction of apoptosis in an animal with a compound of formula I as is claimed in claim 1, page 2 in the amendment filed 4/20/02 at paper no. 13 C.

112, first paragraph rejection of the term "inflammation in claims 1, 5, 26, and 79

The applicant traverses this rejection asserting that the treatment of inflammation is discussed in the specification and is thus enabled. It is unclear as to what type of inflammation the claimed invention is treating, since inflammation is such a broad category that results from several disease states. The applicant has not demonstrated that the claimed invention, can treat this broad category of inflammatory diseases which the applicant is claiming.

112, second paragraph rejection of the term "inflammation" and "cancer" and "drug resistant canc r"

The applicant traverses the rejection of claims 1, 5, 26, 30 and 79 for the term "inflammation" asserting that there is no statutory requirement that applicants list each and every member of a genus within a claim. However, the applicant has not demonstrated that the claimed invention can treat such a broad category of inflammatory diseases, drug resistant cancers or cancers and it is unclear as to actually what inflammation is being treated, since there is a vast array of inflammatory states associated with various disease states and there is a vast array of cancers, and drug resistant cancers. The applicant asserts that the examiner has not provided any evidentiary support for an assertion that the word "cancer" would not be readily understood by those of ordinary skill in the art at the time the invention was made. However, the applicant has not demonstrated in the specification, that the claimed invention can treat any and all cancers, as the word "cancer" delineates or drug resistant cancers. Since the applicant's drug can not treat every cancer or drug resistant cancer, it is unclear as to which cancer and drug resistant cancer the claimed invention can treat as claimed.

112, second paragraph rejection of the term "cancer chemtherapeatic agent"

The applicant has also traversed this rejection, asserting that the there is no statutory requirement that applicants list each and eery member of a genus within a claim. However, the examiner notes that the applicant has not even listed one example in the claim of what a cancer chemotherapetuic agent would be in claim 64. So it is unclear as to what agents are being claimed. If it is unclear as to which agents are

being claimed, certainly it would e unclear as to which pharmaceutically acceptable salts of these agents are being claimed.

Rejection of Trademarks under 112, second paragraph in claim 65

The applicant traverses the 112, second paragraph rejection of tradenames in claim 65, alleging that M. P. E. P. 608.01 (v) supports the use of registered trademarks.

However, the examiner notes that the M. P. E. P 608.01 (v) also states that a trademark that has a fixed and definite meaning, constitutes sufficient identification unless some physical or chemical characteristic of the article or material is involved in the invention. The applicant neglected to note this portion of the M. P. E. P. in the response. Since a chemical characteristic, in this case, the actual cancer chemotherapeutic agent itself, is being referred to by the trademark, the use of a trademark here is not appropriate.

Claims 25, 34-38, 40-41, 66-72, 76-77, 82-83, and 91 are objected to because they are based on a rejected claim and/or are duplicates of another claim.

Claims 42, 44, 45, 63-65, 75, 78, 80, 81, appear to be allowable as they read on the examined subject matter.

The IDS at paper no. 19 has been considered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers

for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Alan L Rotman

ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Binta Robinson

July 1, 2003